10/585606

WO2005/065603

PCT/EP2005/000048

AP20 Rec'd PCT/PTO 10 JUL 2006

Wound covering

The invention relates to a wound covering.

5

10

It is generally known that the healing of wounds can be improved by a moist environment. Scab formation is prevented at the same time and scars seldom occur. The moist environment can be produced by media assisting wound healing. Customarily, for this purpose an absorbent material is impregnated with such a medium and then applied to a wound.

A wound plaster is known from DE 297 21 345 U1 in which a liquid chamber is provided between an adhesive film and a wound nonwoven. The liquid chamber can be placed such that liquid contained therein can thereby penetrate the wound nonwoven.

DE 196 31 421 Al discloses an antimicrobial wound covering. The wound covering consists of a hydrophobic, bacteria-adsorbing material which contains an antimicrobial active compound which is not released into the wound. By means of the hydrophobic material in combination with the antimicrobial active compound, the bacteria from the wound fluid are adsorbed on the wound covering and destroyed there. By the removal of the wound covering, the bacteria are also removed. They thus no longer interfere with the course of healing.

30

35

A plaster is known from DE 197 27 032 Al in which an adherent area is provided with a first adhesive zone and a second adhesive zone arranged outside the first adhesive zone. The adhesive power of the first adhesive zone is lower than that of the second adhesive zone.

A plaster is known from DE 198 60 759 C2 by means of which a skin surface can be covered into which an

15

30

35

injection is to take place. The plaster consists of an elastic surface which has adhesive surfaces on the skin side, between which is arranged an annular medicinally active carrier of an absorbent material. The carrier contains a disinfectant for the disinfection of the injection zone enclosed by the carrier. The elastic surface is provided above the injection zone with an opening and a protective film which covers the adhesive surface and the medicinally active carrier and has to be removed before use.

An adhesive dressing having an adhesive composition in the form of a layer containing at least one section of an adjustable reinforcement is known from DE 697 18 035 T2. The adhesive composition and the reinforcement are selected such that the adhesive dressing is vapor-permeable.

A wound dressing for sticking onto the skin is known from EP 1 005 301 Bl, a first area being provided which is opposite to a substrate which is provided for contact with a wound. The first area is surrounded by a second area which comprises an antimicrobial active compound in order to prevent migration of microorganisms into the first area from the external environment.

A multilayer dressing material is known from WO 02/056927 A2. It contains an absorbent layer, a gaspermeable but liquid-impermeable outer layer and a chamber in the absorbent layer for the release of a liquid treatment medium. The dressing material further contains a perforated layer forming a covering on the wound. The outer layer can be provided with an adhesive layer which makes possible fixing of the dressing material around the wound. By means of this dressing material, it is possible to keep a wound occlusive and moist.

It is the object of the present invention to make available a wound covering which makes possible even better wound healing. A process for its production should further be indicated.

5

This object is achieved by the features of claims 1 and 27. Advantageous embodiments result from the features of claims 2 to 26.

According to the invention, a wound covering 10 provided comprising a first layer formed by an antimicrobially active absorbent matrix and an substance, the substance being present chemically or physically bonded to one surface of the matrix. The surface of the matrix including the substance is coated 15 with a hydrophilic polymer. The matrix contains fibers and can consist of a nonwoven, of gauze, a foam material or another soft absorbent material. A foam material has the advantage that it can bind material discharging from the wound and thereby can be kept 20 remote from the wound, so that it does not interfere with the healing process. The matrix can contain at least one fiber or be formed from at least one fiber. The surface of the matrix, to which the substance is bound, can then be a surface of the fiber. 25 substance is preferably bound to the fiber or surface of the matrix such that it cannot or can barely be floated away from the matrix in the case of use as

30

intended.

A matrix or fiber in which the substance is present bound to the surface of the matrix or fiber can be produced, for example, by treating a polymer forming the matrix or fiber with the substance to produce the matrix or fiber. In the resulting matrix or fiber, some of the substance is present on the surface of the matrix or fiber. A larger part, however, is customarily embedded in the matrix or fiber by the polymer such that it is not accessible to liquid from outside.

10

15

20

25

Preferably, the substance is therefore exclusively bound to the surface of the matrix or fiber. As a result, in production an unnecessary amount of the substance must not be employed which is finally inaccessible.

A prerequisite for good wound healing is that in the and a liquid surrounding the matrix no proliferation of undesired microorganisms occurs. order to prevent this, the wound covering contains the antimicrobially active substance. A substance is antimicrobially active if it significantly delays or completely suppresses proliferation the of microorganisms, measured as described in DE 197 58 598 A1. An antimicrobially active substance is also a which, by conversion, produces substance an antimicrobial active compound in the environment which the wound covering is to be used as intended. If, for example, the antimicrobial active compound is a metal ion or an ionic complex comprising the metal ion, the metal, its alloys and other substances from which the metal ion or the ionic complex comprising the metal ion can be released in the area of a wound are also antimicrobially active. The metal ion can be a silver, zinc cation. The antimicrobially active copper or substance can then be metallic silver, copper or zinc or an alloy or another substance from which the ion mentioned can be released in the area of a wound.

antimicrobially active substance 30 The can be antimicrobially active against Staphylococcus epidermidis or other microorganisms. The antimicrobial activity of the substance with respect to other microorganisms is determined according to the process 35 known from DE 197 58 598 Al using the microorganism to be investigated in each case instead of Staphylococcus epidermidis. Particularly preferred substances are those which are antimicrobially active against one or more of the microorganisms from the group consisting of Bacillus, Clostridium, Enterobacter, Escherichia, Pseudomonas, Salmonella, Staphylococcus, Yersinia, Candida and Aspergillus.

has been found that an antimicrobially active It substance, in particular if it is cytotoxic, can interfere with wound healing. The antimicrobially active substance is cytotoxic if it has a cytotoxic action as described in DIN-ISO 10993-5. In order to prevent interference, it is provided according to the 10 invention that the substance is bonded to the surface of the matrix or the fibers of the matrix. By binding, it can be prevented that the antimicrobially active substance gets to an amount in the wound interfering with wound healing. Furthermore, it can be prevented 15 thereby that the antimicrobially active substance is lost from the area of the wound covering by absorption into the body and as a result can no longer be antimicrobially active there long-term. Furthermore, it can be prevented thereby that the substance induces 20 undesired, e.g. allergic, reactions in the body after absorption.

By means of the wound covering according to the invention, microorganisms originating from the wound, 25 for example, can be prevented from proliferating in the wound and then leading to an infection or reinfection of the wound. By means of the long-term prevention of microorganism growth, the wound covering can be left on the wound until healing of the wound. As a result, 30 mechanical stress on the wound by removal of the wound covering can be avoided and resting of the wound favorable to wound healing can be guaranteed. The main advantage of the wound covering according to the 35 invention consists in the fact that the wound covering itself remains microorganism-free, while the wound healing process is not disturbed by the antimicrobially active substance.

10

15

20

25

30

The coating of the polymer is designed to be so thin and the polymer is chosen such that the action of the substance is not prevented thereby. Such a polymer can be, for example, a polymer formed from hexamethyldisiloxane by plasma polymerization. The improves the binding of the substance to the fiber or the matrix. For example, clusters of silver applied by deposition are protected and evaporation mechanical abrasion. Owing to the hydrophilicity of the layer, the wettability of the fiber or of the matrix is favored. A more uniform distribution of the liquid over the matrix is thereby achieved. Furthermore, a better action of the antimicrobially active substance can also be achieved by means of the improved contact of the fiber or of the matrix with the liquid. Moreover, by means of the hydrophilic polymer, in particular formed by plasma polymerization, an adhesion of gram-positive and/or gram-negative microorganisms to the fibers or decreased. be Furthermore, the matrix can hydrophilic layer improves the gliding behavior of the matrix or individual fibers of the matrix in the moist environment, because a liquid film is formed directly on the surface of the coated matrix or fiber. If the matrix then lies on the wound, in the case displacement it glides easily over the wound and in the course of this exerts only a low mechanical stress on the wound. As a result, in the case of a decreased liquid cushion between the matrix and the wound, the wearer comfort of the wound covering is markedly increased. Moreover, the liquid film on the coated fiber or matrix can also prevent the growth of the tissue newly formed in the wound into the matrix.

Preferably, the wound covering has a second layer formed by a gas-permeable but liquid-impermeable film connected to the matrix and a self-adhesive first area. The matrix is connected to the film in a second area. The matrix can be connected to the film, for example, in such a way that it is stuck together with or bonded

to the film. The self-adhesive first area is an area of the film which surrounds the second area, preferably at a distance, it being possible to stick the wound covering to human or animal skin by means of the self-adhesive first area. As a result of sticking on, a liquid-tight inner space which can be filled with a liquid comprising the matrix is formed. The inner space makes possible liquid wound care.

This embodiment of the invention is based on the knowledge that during customary moist wound treatment the absorbent material begins to dry at an advanced phase of wound healing and the wound as a result extracts moisture. As a result, the course of wound healing is adversely affected.

Furthermore, this embodiment of the invention is based on the knowledge that wound healing can additionally be improved by the wound not only being kept moist, but being supplied with so much liquid that a liquid 20 cushion is formed over the wound. As a result, wound healing is improved and the tendency for scar formation is reduced. Such wound care is designated here as liquid wound care. Using the wound covering according to the invention, this can be achieved by first placing 25 the wound covering dry on the wound to be treated and firmly sticking it to the skin surrounding the wound by means of the self-adhesive first area such that the sealed liquid-tight as area is a wound Subsequently, the film can be pierced by means of a 30 liquid can be injected into the cannula and a underlying inner space. After the withdrawal of the cannula, the resulting opening in the film can be sealed by means of an adhesive film. Advantageously, the liquid is administered a number of times, e.g. once 35 per day. As a result, it can be ensured that the wound is permanently kept under a liquid cushion until healing and until the removal of the wound covering.

Preferably, the self-adhesive first area is provided with an adhesive which is highly skin-compatible and is not dissolved by an aqueous liquid. Such adhesives are known in the prior art, in particular in the field of plasters. Furthermore, the adhesive should also withstand an increased liquid pressure in the inner without being detached from the skin. An increased liquid pressure can already be generated by the injection of the liquid and a tension exerted by film. An increased liquid pressure can, for example, also be caused by a mechanical stress on the wound covering by the patient, e.g. by a movement of the body part containing the wound.

By virtue of the fact that the matrix is connected to 15 the film, the matrix can be raised from the wound by means of the liquid cushion. As a result, the wound is not directly in contact with the matrix and the antimicrobially active substance. By raising the matrix from the wound, undesired growth of tissue newly formed 20 in the wound into the matrix can also be avoided. A perforated layer forming a covering on the wound and separating the wound from the matrix, as is known from WO 02/056927 A2, is therefore not necessary. The matrix serves here as a carrier for the substance and not for 25 the purpose of keeping the wound moist, as is the case with the known wound coverings. The raising of the matrix from the wound can be favored by the selfadhesive first area being arranged at a distance from a second area, to which the matrix is connected by the 30 film.

Antisepsis of the wound can be achieved by means of an appropriate choice of the liquid. For example, the pH of the liquid can be so low that as a result growth of microorganisms is prevented. A liquid having a low pH moreover has an astringent action on the wound, whereby the healing process can be favored. Furthermore, the

15

20

25

30

35

solution can contain factors and/or nutrients stimulating cell growth.

Preferably, the substance is an inorganic substance, in particular a metal or a metal compound. Such an active substance antimicrobially is inexpensive, easily obtainable and easy to process. A metal compound here is understood as meaning a mixture or an alloy of at least two metals. Metal ions or complexes comprising metal ions can be formed from the metal or the metal compound as active compounds and released. Preferably, an oligodynamically, i.e. in very small amounts, antimicrobially active metal oligodynamically antimicrobially active metal compound is concerned.

In a preferred embodiment, the substance is selected from a group consisting of silver, copper and zinc, their ions and their metal complexes or a mixture or alloy comprising at least one of these components. In addition to the metals mentioned, the alloy can in particular also contain gold and/or platinum. Such a substance acts against a large number of different microorganisms and intervenes in their metabolism in numerous ways. Accordingly, on use of such a substance resistance formation in bacteria occurs more rarely than when using specifically acting organic antimicrobial substances, such as antibiotics. Preferably, the substance is silver, a silver cation or a silveror silver cation-releasing complex or a silver- or silver cation-releasing alloy. In particular, metallic silver is easily processable and obtainable in high quality at a comparatively low price, such that the wound covering according to the invention can also in turn be produced comparatively inexpensively.

The metal or the metal compound can be applied to the fiber or to the surface of the matrix in the form of clusters, in particular by evaporation and deposition,

15

20

25

30

35

by a sputtering process or by chemical vapor deposition. In the case of evaporation and deposition, the metal or the metal compound is evaporated thermally in a vacuum and the metal vapor is subsequently deposited on the fiber or the matrix. The metal or the metal compound is present on the fiber or the matrix in the form of clusters as a result of application by means of evaporation and deposition, the sputtering process or chemical vapor deposition. The clusters have particularly good antimicrobial properties.

Expediently, the substance is present in the wound covering according to the invention in granular form, a mean grain or particle size of 5 to 100 nm being preferred. The substance can be present in the form of individual particles or particles interlinked with one another. Such fine powders of antimicrobially active substances can be easily produced, in particular for inorganic substances, and here in particular for silver, but also for copper and zinc, and mixtures, complexes and alloys of the three metals mentioned. On account of the low mean grain size, the substance has a high specific surface area, so that it can be readily released from the matrix, in particular by diffusion. Furthermore, it is advantageous that, on account of the high specific surface area, chemical inactivation of the granular active compound, as can occasionally occur in a wound environments, usually only relates to a part of the surface, such that release of the substance from the matrix is made possible even under adverse conditions. A mean grain size of the substance of 5 to 50 nm, preferably 5 to 20 nm, has proven particularly advantageous. If the substance is silver or a silver alloy, these grain size distributions are also referred to as nanoscale silver or a nanoscale silver alloy.

The substance can be present in a layer thickness of at least 1 nm, and preferably not more than 1 mm. When

using granular substances, the layer is at least as thick as the granular active compound. Preferably, the mean layer thickness is at least 5 nm to 100 nm, layer thicknesses of 10 nm to 50 nm being particularly preferred, in particular if the substance is silver, copper and/or zinc or their ions, metal complexes or a mixture or alloy of these elements. It has been shown thicknesses such small layer even that antimicrobial substance, in particular comprising nanoscale silver, are adequate in order to be able to achieve an antimicrobial but not cytotoxic action.

The substance is preferably present in an amount such that it acts antimicrobially in the case of thorough soaking of the matrix with a liquid in the matrix, in particular in the entire matrix. Such an amount can be determined by means of simple routine tests. If the substance is metallic silver, an adequate antimicrobial action in the matrix can be achieved by a silver content of the matrix of 1 µg to 200 µg per cm² of an area maximally coverable the matrix. Higher silver contents are disadvantageous, because silver ions can be released in such an amount that these have an adverse effect on wound healing.

25

30

10

15

20

Preferably, the polymer is a polymer decreasing the adhesion of bacteria, preferably gram-negative bacteria or staphylococci, in particular Staphylococcus epidermidis, to the fiber or matrix. In addition to the substance, this measure also causes a decreased colonization of the matrix with microorganisms.

Preferably, the fiber or surface of the matrix is coated with the polymer by means of plasma polymerization. As a result, an extremely thin embodiment of the layer is made possible, which barely adversely affects the action of the substance. By means of the choice of the parameters during the plasma polymerization, the properties of the polymer can be

15

20

25

influenced. By carrying out customary routine tests, the person skilled in the art can determine suitable starting materials and parameters for the production of an appropriate polymer layer. The coating of the matrix with the antimicrobial substance and the plasma polymerization can be carried out, for example, as follows:

In a first step, clusters of nanoscale silver are applied to a matrix consisting of a nonwoven. For this purpose, metallic silver is evaporated at approximately mbar working pressure under a protective 10 atmosphere of, for example, argon. In this process, silver is deposited on the matrix in the form of individual silver particles or silver particles interlinked with one another. The mean particle size of the silver particles is approximately 10 to 20 nm. The silver is applied in a thickness of approximately In a second step, a plasma polymer layer containing hexamethyldisiloxane (HMDSO) is applied as a monomer or precursor. The plasma polymerization is carried out at a working pressure of 0.07 mbar using a working gas of 95% O₂ and 5% HMDSO. After 45 seconds of the plasma polymerization thus carried out, the silver applied is provided with a 45 nm thick and strongly hydrophilic plasma polymer layer. The surface energy of the coating here is 105 mN/m.

The application of the polymer to the fiber can take place before preparing the matrix from the fiber or afterward. If it takes place afterward, the entire matrix, for example a nonwoven or a textile fabric, is subjected to a coating process, such as plasma polymerization. It is particularly advantageous if the polymer is oxidized after the plasma polymerization. As a result, an extremely hydrophilic surface area can be created.

Scanned ...

6779779006

In a preferred embodiment, the polymer is formed from monomers based on acrylic acid or from monomers based on siloxane, in particular hexamethyldisiloxane. Such a polymer can combine antiadhesive properties to bacteria with good hydrophilic properties. It further allows a good action of a substance covered by the polymer on the matrix, such as, for example, metallic silver.

The polymer is preferably present in a layer having a mean thickness of 5 nm to 500 nm. In particular, in the case of a plasma-polymerized polymer, however, it is preferred if the thickness is 5 to 200 nm, preferably 10 to 100 nm. At these layer thicknesses, in particular with polymer layers produced by plasma polymerization, outstanding antimicrobial and noncytotoxic coatings can be produced. At the same time, these coatings are very thin, such that visually they are barely noticed or can even be transparent.

in which the 20 Preferably, the amount substance present is calculated such that the amount of active compounds formed and/or released by the substance does not act cytotoxically on a wound in the application case. Such an amount can be determined by means of 25 simple routine tests. The active compounds can be, for example, metal ions or complexes of these metal ions. If the substance is silver, a suitable amount of silver in the matrix is, for example, 1 µg to 200 µg, preferably 5 µg to 35 µg, in particular 5 µg to 15 µg, per cm² of an area maximally coverable by the matrix. It 30 has previously not been recognized that silver ions could be released by the silver-containing wound coverings customarily used in amounts which act cytotoxically on wounds. As a result, wound healing can 35 be disturbed.

Preferably, substances assisting wound healing, in particular growth factors, are bound to the matrix. Such substances can be, for example, the epidermal

growth factor (EGF), the platelet growth factor (PDGF), the vascular endothelial growth factor (VEGF) or the keratinocyte growth factor (KGF). Preferably, the matrix is thoroughly soaked or impregnated with a liquid assisting wound healing, in particular an acidic liquid or a liquid comprising nutrients assisting wound healing.

In a particularly preferred embodiment, the film is transparent, at least in places. As a result, the liquid level below the film can be observed and new liquid can be refilled as soon as a decreased liquid content is observed in the inner space.

In a further particularly advantageous embodiment of the invention, the entire wound covering, including matrix and film, is transparent to light, in particular UV light, infrared light (IR light) or near infrared light (NIR light).

20

25

30

35

This can be achieved by the choice of an appropriate material. As a result, it is possible to subject the wound to phototherapy without removing the wound covering. Phototherapy can considerably accelerate wound healing.

Preferably, the wound covering contains an indicator. The indicator can be a dye which indicates a certain state of the wound covering or the wound. For example, a pH indicator can be concerned here which can change its color depending on the pH. The color change can be observed through the film, which is transparent at least in places. The indicator can also be formed from a majority of substances which interact in order to indicate a certain condition. The indicator can also be a sensor. The sensor can be, for example, a conductive polymer which changes its conductivity according to the state of the wound or wound covering. The sensor can also be a biosensor. A biosensor is understood as

15

20

25

meaning a measuring probe in which the biomolecules are to transducers, such as, for coupled example, potentiometric sensors. The transducers convert signal resulting on binding of a specific substance to the biomolecule to an electrical signal. The sensor can be part of a sensor field or biosensor field comprising a number of sensors. By means of different sensors, a number of parameters characterizing the state of the the wound covering can be determined wound or simultaneously.

indicator can also be an indicator which The indicate the liquid content of the matrix. As a result, drying of the matrix can be detected better earlier. The indicator can also be an indicator which can indicate the degree and/or type of a microbial contamination of the matrix or of the wound. This can be achieved, for example, by means of an immunological indicator. In this case, for example, microorganisms or parts of microorganisms can be specifically bound by an antibody and a color reaction induced as a result. The indicator can also be an indicator which can indicate an inflammatory status of the wound. Such an indicator can likewise be an immunological indicator. In this case, inflammatory factors can be specifically bound by an antibody and a color reaction induced as a result.

Furthermore, the invention relates to a process for the production of a wound covering according to the invention, having the following steps:

- making available of an absorbent matrix,
- making available of a gas-permeable but liquidimpermeable film,
 - application of a self-adhesive first area (16) on or to the film and

connection of the absorbent matrix to the film in a second area of the film,

the first area surrounding the second area of the film,

5

10

15

20

25

by means of evaporation and deposition, a sputtering process or chemical vapor deposition first an antimicrobially active substance and then, by plasma polymerization, a polymer being deposited on the matrix or a fiber forming the matrix.

The matrix can be a nonwoven, a gauze, a foam material or another soft absorbent material. The substance and the polymer can be deposited on the finished matrix. The fiber forming the matrix must not be a fiber which forms the matrix exclusively. The fiber forming the matrix can be a fiber which is incorporated into the matrix during or after the production of the matrix. By means of the evaporation and deposition, the sputtering process or chemical vapor deposition in combination with plasma polymerization, it is possible to achieve a particularly thin and simultaneously antimicrobially highly active application of the substance particularly thin application of the polymer having specific properties to the fiber or matrix. Only a small quantity of substance and/or polymer is needed. substance is protected by the polymer, The particular from mechanical abrasion.

- One embodiment of the invention is explained in more detail below by way of the drawings, in which:
- Fig. 1 shows a schematic representation of the wound covering according to the invention in a side view,
 - Fig. 2 shows a schematic representation of the wound covering according to the invention in a top view and

15

20

25

30

35

Fig. 3 shows an arrangement of graphic representations of the time course of the growth of bacteria, measured in the form of optical density (OD) of a medium, in contact with a conventional matrix and a matrix of a wound covering according to the invention.

Fig. 1 and 2 show a wound covering 10 according to the invention having an absorbent matrix 12, a gaspermeable but liquid-impermeable film 14 and a self-adhesive first area 16. The first area 16 is here an area of the film to which an adhesive is applied. The first area 16 here surrounds a second area 17 of the film contacting the matrix. On use of the wound covering 10 as intended, the matrix 12 is placed on the wound 18 and the self-adhesive first area 16 is stuck all around together with the skin surrounding the wound 18. Subsequently, a liquid can be injected through the film 14 into the inner space formed by sticking together. The hole formed on injecting into the film 14 is sealed by means of an adhesive film.

In an application study, in a first patient group a wound covering according to the invention having a matrix was employed whose fibers had been coated with silver and a hydrophilic polymer formed by plasma polymerization from hexamethyldisiloxane. The wound covering was in this case employed over at least 4 days for postoperative liquid wound care in the clinical picture of Pectus excavatum (funnel chest). In a second patient group serving as a control, conventional wound care was carried out. While in the second group infections occasionally occurred, in the first group no infections were observed. Moreover, the wearer comfort of the wound covering according to the invention was distinctly better than in the case of the wound covering employed for conventional wound care due to the hydrophilic coating. The liquid wound care with the wound covering according to the invention made possible a more rapid healing with a lower tendency for scar formation. The matrices of the wound coverings employed for wound care were also still antibacterially active after 4 days on a wound, as has been shown in the experiment presented in Fig. 3.

The results shown in Fig. 3 have been determined according to the process known from DE 197 58 598 A1. This process is further described in Bechert, Thorsten et al., Nature Medicine (2000), Vol. 6, No. 8, pages 1053 to 1056. The disclosure content of the two aforementioned documents is included here. The matrices to be tested were employed as described in the test.

15

10

In Fig. 3, each field shows an x-y graph, in which the time is plotted on the x-axis and the optical density is plotted on the y-axis. The experimental results shown in columns 1, 2, 4, 5, 11 and 12 of Fig. 3 have been determined in parallel experimental batches A to H corresponding to rows A to H using the following matrices:

Column 1, rows A-H:

matrix uncoated,

25

20

Column 2, rows A-H:

matrix coated with silver and a polymer formed from hexa-methyldisiloxane by plasma polymerization,

30

Column 4, rows A-H:

matrix coated with silver and a polymer formed from hexamethyldisiloxane by plasma polymerization from a first wound covering used for 4 days in the above application study,

35

Column 5, rows A-H:

matrix coated with silver and a polymer formed from hexamethyldisiloxane by plasma polymerization from a second wound covering used in the above application study for 4 days,

Column 11, rows A-H:

sterile controls

10

20

25

5

Column 12, row A:

positive control

Column 12, row B:

negative control

Column 12, row E, F: blank value 15

In the case of the sterile controls, in each case only medium without addition of Staphylococcus epidermidis was employed in order to show that the bacterial growth did not result from the medium. In the case of the positive control, a metallic silver-containing polymer was employed. The values show that the bacteria employed are sensitive to silver and can be destroyed by it. In the case of the negative control, the same employed that, however, contained no polymer was silver. The blank value is a value measured in an empty hollow of the microtiter plate, which is to be subtracted in an evaluation of all measurements.

The experimental results show that the matrix of the 30 wound covering according to the invention coated with and the polymer formed from hexamethyldisiloxane by plasma polymerization has a highly antibacterial or bactericidal action. This action is

also still present after 4 days on a wound. 35